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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,881	12/22/2000	Norman G. Anderson	2316-143	5632
7590	04/20/2004			
John C. Robbins Large Scale Biology Corporation 3333 Vaca Valley Parkway Suite 1000 Vacaville, CA 95688			EXAMINER PADMANABHAN, KARTIC	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/741,881

**Applicant(s)**

ANDERSON, NORMAN G.

**Examiner**

Kartic Padmanabhan

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is the way in which particles are sedimented across the first slanted solid phase. If the solid phase is slanted, the fluid will just flow down the solid phase without anything being sedimented, absent some other step.
4. Claims 1 is rejected as vague and indefinite for the recitation of allowing particles to bind to the immobilized binding agent. If there are multiple binding agents (as recited in claim 2), is the claim stating that the particles only bind to one of them, or to all of them? In addition, in line 12 of the claim, applicant has referred to the "second slanted solid phase"; however, applicant has never recited the second solid phase as slanted previously on the claim, such that there seems to be a lack of antecedent basis for this term.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suovaniemi (US Pat. 4,290,997) in view of Anderson et al. (US Pat. 6,254,834).

Suovaniemi teaches a method and apparatus for measurement of agglutination tests, wherein the reaction vessel may be a cuvette that is made such that its bottom is at an angle. The measuring vessels may be separate cuvettes or may be a matrix of several cuvettes, which matrix can be made by transfer molding out of plastic, like the cuvette block of the FP-9 system (Col. 4, lines 18-34). When sample is added to the cuvette, non-agglutinated particles are sedimented in the bottom of the cuvette; however, agglutinated particles are found along the whole length of the slanted bottom of the cuvette (Col. 5, lines 20-28 and Fig. 6). Further, the slanted portion of the cuvette may have specific antigens or antibodies attached thereto, such that the agglutination complexes adhere more firmly to the cuvette surface. Coloring or fluorescent agents, or any other measurable agent may also be added to the agglutination complex (Col. 4, lines 4-12). The complexes are then detected. The method of the reference allows for the measurement of the results of various agglutination tests. The method of the reference is performed with red corpuscles; however, the reference states that agglutination tests are routinely performed with

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bacteria and viruses (Col. 1). The reference does not teach the use of an additional slanted solid phase to concentrate the particles.

Anderson et al. teach methods for the detection and characterization of microorganisms using sedimentation rate and binding density. The method comprises ultracentrifugation of a sample containing the microorganisms in an ultracentrifuge tube to concentrate them. This ultracentrifugation step may include the formation of density gradients and/or the staining of the microorganisms using fluorescent dyes (Col. 5, lines 1-19). The centrifuge tube of the reference has a slanted bottom surface, as seen in Figures 2A-2C. The method of the reference may also include the step of exposing the microorganisms to reagents, including detergents, surfactants, and enzymes, contained and immobilized in distinct zones in a density gradient to dissolve contaminating particles (col. 6, lines 42-50). In addition, fluorescent particles of known density may be included in the sample to assist in identifying particles by density (Col. 13, line 65 – Col. 14, line 10). However, the reference only teaches restricting the movement of reagents within the second slanted solid phase and does not teach reagent immobilization.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to concentrate the particles of interest over a slanted solid phase as in Anderson et al. with the method of Suovaniemi, as this would allow for greater binding efficiency. One of skill in the art would have known that the greater the concentration of target analyte in a given area, the greater the binding efficiency to any binding agents they contact. In addition, it would have been obvious to stain the particles because Suovaniemi states that any detectable agent may be added to the complex.

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***Response to Arguments***

8. Applicant's arguments with respect to claims 1-10 and 28-30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Claims 1-10 and 28-30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

04/19/04